

Exhibit H

**Deposition of Phyllis Lambridis
January 18, 2010**

Phyllis A. Lambridis
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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

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IN RE: DIGITEK PRODUCTS : MDL NO.
LIABILITY LITIGATION : 1968

(This document relates to all cases.)

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CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

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Wayne, New Jersey
Monday, January 18, 2010

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Videotaped Deposition of PHYLLIS A.
LAMBRIDIS, held at Ramada Inn, 334 US Rt. 46,
on the above date, beginning at 9:06 a.m.,
before Kimberly A. Otherwise, a Certified
Realtime Reporter and Notary Public.

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1 supposed to have?

2 A Yes.

3 Q Do the FDA regulations also require
4 that the company have an effective quality
5 control unit with appropriate responsibility
6 and authority?

7 A Yes.

8 Q Now, you worked at Actavis, you
9 said, in 2007 and 2008; correct?

10 A Yes.

11 Q According to FDA, during that period
12 of time, was there a total failure of the
13 quality system at Actavis?

14 A Can you repeat that?

15 Q Yes. During that period of time
16 between 2007 and 2008, according to the FDA
17 investigators, was there a total failure of
18 the quality system?

19 A According to the investigator, yes.

20 Q I'm going to show you what I'm going
21 to mark as 106 to your deposition.

22 Can we put up -- it's 543001.

23 (Plaintiff's Exhibit No. 106
24 was marked for identification.)

1 2006, and then there was a follow-up
2 inspection in 2007 immediately before you
3 started to work for the company?

4 A It started before I joined, yes.

5 Q So then if we go to the next
6 paragraph, this paragraph is referring to the
7 2008 inspection; correct?

8 A I'm sorry. Which page?

9 Q Page 2. I'm sorry. Next paragraph.

10 A Yes.

11 Q Okay. So it says: This inspection
12 was limited to coverage of the quality system
13 due to significant CGMP deficiencies including
14 but not limited to out-of-specification
15 in-process, finished product, and stability
16 results for more than -- and somebody's
17 redacted the number -- prescription
18 pharmaceutical products; release of digoxin
19 tablets, .125 milligrams, Lot 70924A2,
20 following visual inspection of the -- and then
21 there's another word blacked out -- to remove
22 double thick tablets; failure of the quality
23 unit to reject products not meeting
24 specifications, to complete quality assurance

1 investigations, to expand investigations to
2 other lots and products, to file NDA field
3 alerts within time frames, and to respond to
4 out-of-specification products on the
5 marketplace. Analytical methods requiring
6 remediation remained in use and
7 approximately -- the number is blacked out --
8 prescription drug products had no analytical
9 evaluations of impurities on stability.
10 Written procedures were not followed and
11 changes with potential product quality impact
12 were not all reviewed and approved by the
13 quality unit. No market action was taken by
14 the quality unit for any products on the
15 market at the initiation of the inspection,
16 despite the confirmed out-of-specification
17 in-process, finished product, and stability
18 results.

19 Now, was that what the general
20 description of the inspection in March of 2008
21 was about?

22 A Description of the outcome of the
23 inspection.

24 Q And it says -- in the sentence just

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1 discuss the upcoming exit meeting; correct?

2 A Correct.

3 Q And then if you look at the top of
4 the next page, does it say there: "Both
5 Ms. Eyjolfsdottir and Ms. Lambridis
6 acknowledged the severity of the cGMP
7 deficiencies and stated the need for
8 corrective actions, restructuring of the
9 Quality Unit, and hiring"?

10 Do you see that?

11 A Yes.

12 Q And do you recall making that
13 admission?

14 A Yes.

15 Q And it was accurate and correct?

16 A Based on what was presented to us,
17 yes.

18 Q Right. And part of this, these
19 deficiencies involved the drug Digitek;
20 correct?

21 A Yes.

22 Q Now, if you'll go over to Page --
23 I'm going to skip a few pages now -- Page 15,
24 do you see there's a paragraph there that

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1 BY MR. BLIZZARD:

2 Q Were there additional problems
3 with -- let me ask you this: Did the quality
4 system that was in effect at Actavis, did it
5 cover all the drugs manufactured by Actavis?

6 A The quality system would cover the
7 entire facility, yes.

8 Q Okay. So there weren't any drugs
9 that were excluded from the operation of the
10 quality system; quality applied to each of the
11 drugs; right?

12 A Yes.

13 Q So were there problems with the
14 quality system in September of 2008?

15 MR. DEAN: Objection. It's
16 vague and ambiguous. You've already
17 established they weren't making product
18 at that point, Ed. Could you clarify
19 that?

20 (Plaintiff's Exhibit No. 118
21 was marked for identification.)

22 BY MR. BLIZZARD:

23 Q Let me just show you a document
24 that's marked as Exhibit 118. This is

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1 specific comments about non-Digitek
2 drugs, I think that is beyond the scope
3 of what's in PTO-12 and 27. If you're at
4 a general level, I'm okay with it. But I
5 think your last question could lead her
6 to go into specifics. And I'm just
7 instructing her, as to specifics, to
8 limit it to Digitek.

9 BY MR. MILLER:

10 Q If you understood all those
11 instructions, ma'am, it's okay to answer.

12 A I think I can answer it. In the
13 case of Digitek and with some of the other
14 drugs that were recalled, I didn't always see
15 the logic in extending it to all batches. And
16 that doesn't mean that I didn't execute on all
17 batches because there was -- when you're
18 dealing in a situation as I was in, you get to
19 a point where you just -- in order to advance
20 to the next point and not belabor the point,
21 there's certain concessions that are made.

22 So in the case of some of the other
23 recalls, which based on his instruction, I'm
24 not going to give you the detail, but there

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1 going to cover some statements that have
2 already been covered.

3 MR. MILLER: If you would
4 enlarge the summary of the establishment
5 inspection report that was discussed
6 earlier.

7 THE WITNESS: Could I have a
8 copy?

9 BY MR. MILLER:

10 Q You certainly may.

11 That summary was already read into
12 the record earlier, but I'll read the first
13 sentence again: An inspection of this large
14 generic prescription pharmaceutical
15 manufacturer was conducted as a qualifying GMP
16 inspection of a new site, 990 Riverview Drive,
17 Totowa, as per FACTS Assignment -- and it
18 gives the number, Operation ID, number.

19 When it states that it's an
20 inspection to qualify the GMP department, am I
21 paraphrasing that right?

22 A There's no GMP department. It's
23 doing a general GMP inspection of a site.

24 Q And when you use the term "general

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1 GMP inspection," would they look at good
2 manufacturing practices -- if they look at,
3 say, stability and the amount of time that you
4 have in this field, will they go through and
5 qualify GMP stability for every product or do
6 they qualify stability for one or two
7 products? They wouldn't go through 64
8 products? -- is my question.

9 A Correct.

10 Q So there's a general term there
11 where, okay, three or four products or
12 whatever number it might be are approved for
13 GMP for stability, or any other example, then
14 it's approved across the board; is that
15 correct?

16 A They look at the system itself, and
17 they use a sampling of the products to
18 determine if that system's working.

19 Q Would you agree with me that when
20 they look at the system, again, they look at
21 stability; they don't look at stability for
22 each and every of the 64 products; is that
23 correct?

24 A Correct.

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1 Q And does the counterpart hold true?
2 When they come in to inspect, they won't
3 inspect every product's stability testing;
4 they'll inspect a couple and then say you
5 violated the GMP for stability across the
6 board; is that correct?

7 MR. DEAN: Objection.

8 Go ahead.

9 THE WITNESS: If it's not
10 specific to a product, yes, then that
11 would be true. So if they found a
12 problem that was related specifically to
13 one product, then you couldn't make that
14 assumption. But if they found a general
15 problem, then you could.

16 BY MR. MILLER:

17 Q Would you describe a general
18 problem? If they found GMP violations in
19 three or four products out of 64, that then
20 does it become a general problem?

21 MR. DEAN: Objection;
22 incomplete hypothetical.

23 BY MR. MILLER:

24 Q It's okay to answer.

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1 A I was just saying that that's just
2 not the best example to use for that.

3 Q You're in the field. Give me an
4 example.

5 A Say what you were -- what you asked.

6 Q Well, we've identified if one
7 product is tested for something, say,
8 stability, and that one product is the only
9 product that's been found to violate CGMP,
10 that we consider it a one-product problem.

11 In your mind, if there's 65
12 products, how many products have to fail
13 stability before you would say it's a general
14 GMP violation?

15 MR. DEAN: Objection;
16 incomplete hypothetical.

17 Go ahead.

18 THE WITNESS: Their
19 inspectional approach is to look at
20 systems. So there's six systems. So
21 stability is part of a laboratory system.
22 So when they do an inspection, they
23 typically look at a quality system. And
24 even in the quality system, there are a

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1 lot of subcategories based on the
2 different activities that quality
3 performs.

4 So when FDA's review -- they
5 need to review enough to make a -- to
6 draw some kind of opinion of what --
7 whether they feel that that system's
8 working or not.

9 And what you're -- where you
10 were going with that is that if they find
11 one thing wrong, they're not going to
12 necessarily implicate the whole system;
13 but if they find multiple things wrong,
14 then they would implicate the whole
15 system.

16 BY MR. MILLER:

17 Q Yes. And my question is: Being
18 that you've been in the field for so many
19 years and have so much experience, how many
20 multiple -- and by way of example, the
21 laboratory system, stability testing, what is
22 your opinion as to how many products would
23 have to fail or issues in stability,
24 violations of CGMP would they have to find

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1 The next sentence: Although a
2 review of the new laboratory was conducted,
3 comprehensive coverage was not afforded due to
4 the significant deficiencies of the Quality
5 System.

6 Do you recall that due to the
7 deficiencies, significant deficiencies of the
8 quality system, that there was not
9 comprehensive coverage of the laboratory? Do
10 you agree with that statement?

11 A They did not do a full laboratory
12 inspection. As I explained before, there are
13 six systems. Quality is one, packaging is
14 one, manufacturing is one, laboratory is one.
15 So they looked at the quality system only.
16 And as I said, under quality, there's subparts
17 that interact with the lab, so investigation,
18 complaints, things that are related to
19 laboratory testing. So they didn't do -- this
20 is correct in that they did not do a
21 comprehensive review of the laboratory.

22 Q Okay. So when they say "quality
23 systems," what different departments fall
24 under that?

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1 A Mainly QA, but it relates to
2 other -- it relates to all areas. That's why
3 they look at the quality system because it
4 relates to the entire facility. So it
5 involves change control, annual product
6 reviews, investigations, complaint handling,
7 things that would go across the board.

8 Q But you agree that due to the
9 significant deficiencies of the quality
10 system, that comprehensive coverage of the
11 laboratory was not conducted? Do you agree
12 with the statement?

13 MR. DEAN: It doesn't say
14 "comprehensive coverage of the
15 laboratory." You added a word there.

16 THE WITNESS: It says here they
17 did review the new laboratory. So there
18 was an inspection -- part of this
19 inspection included a review of the
20 laboratory at Riverview, but they didn't
21 do the full laboratory GMP inspection.

22 BY MR. MILLER:

23 Q But the plan was to do just that?

24 A The plan was to do a GMP inspection

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1 an EIR.

2 THE WITNESS: Because she
3 justifies her reaction.

4 MR. MILLER: Well, I'm not
5 looking for your answer. I'm looking for
6 her answer.

7 MR. DEAN: I'll clear it up
8 later on. Keep going.

9 BY MR. MILLER:

10 Q Do you agree that specifically --
11 when you look at the paragraph "Specifically"
12 and it says: Although three out of --
13 although three out-of-specification results
14 were obtained for blend uniformity at the
15 Right-Top sample location for digoxin
16 tablets -- and it goes on and on. You've read
17 it.

18 You agree that this is an example of
19 a GMP violation that she recorded during her
20 observation during the 483 inspection?

21 MR. DEAN: Objection to form.
22 Go ahead.

23 THE WITNESS: She -- her
24 observation is the first sentence. And

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1 she's using what she observed with this
2 digoxin to substantiate that GMP issue.

3 BY MR. MILLER:

4 Q And the GMP issue is she's outlining
5 a violation of the GMP issue?

6 A Right. And then the rest of it is
7 her rationale.

8 Q I'm sorry. We stepped on each
9 other. Just to get something clean, her
10 write-up is about a violation of a GMP
11 specific to Digitek?

12 MR. DEAN: Objection to form.
13 Go ahead.

14 THE WITNESS: No. That's why
15 I'm saying it's not specific to Digitek.

16 BY MR. MILLER:

17 Q What is it specific to?

18 A She's using this digoxin example --
19 this example, which happens to be digoxin, to
20 substantiate her claim that determinations of
21 conformance to appropriate written
22 specifications for acceptance are deficient
23 for in-process materials. That's the GMP
24 issue. She's using this as the example. It

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1 happens to be Digitek. So it's not specific
2 to Digitek is what I'm saying.

3 Q Even though it says "specifically"
4 and gives an example?

5 A It says "specifically" to say
6 because every --

7 Q I'm with you. Okay.

8 A Every observation has to be
9 substantiated.

10 Q Okay. So is it specific to the GMP
11 or the quality systems? It's specific to the
12 quality system, not so much for Digitek?

13 A Correct.

14 Q And you agree that Digitek is one of
15 the drugs being inspected by that quality
16 system, so in that way it does affect Digitek?

17 A She's investigating the quality
18 systems for the manufacturing facility that
19 produces Digitek.

20 Q Right. And she has identified a
21 violation of a GMP. And the example that she
22 used to show that the GMP was violated --

23 A Was Digitek.

24 Q -- was Digitek?

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1 A Correct.

2 Q If it was some other product that
3 they make, even if they had said by way of
4 example oxycodone hydrochloride tablets and
5 that was the example, it wouldn't matter
6 because the violation is a general violation
7 that's outlined at the top; right? So it
8 wouldn't have mattered to you --

9 A She's pointing out, yeah, what she
10 observed to be a violation.

11 Q I understand. And if you take a
12 look at Page 45 of 95, now, this issue, this
13 out-of-specification issue goes to -- am I
14 correct in using the term "blend uniformity"?

15 A In the last example?

16 Q Yes.

17 A Yes.

18 Q And blend uniformity is where you're
19 testing to see if the amount of active
20 pharmaceutical ingredient has dispersed evenly
21 in the mixture; is that a good way to put it?

22 A That's a good way to put it.

23 Q And "out of specification" means
24 that a sample that they took did not have the